

Saturday, August 2nd 2014

**Brazil-Japan Seminar on Pharmaceuticals and Medical Devices
Regulations**



Building a New Partnership through Pharmaceuticals



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JAPAN's Pharmaceutical Industry

①	Number of Companies:	349
	• *Research-oriented Companies:	72
②	Number of Employees:	167,514
③	Pharmaceutical Market:	10,016 billion yen
④	Pharmaceutical Production:	6,977 billion yen
	• as a percentage of GDP:	1.48%
	• Prescription Drug Production:	6,263 billion yen

*as of April 1st 2014

1 yen = 0.0218 R\$ = 0.0099 US\$ (as of July 1st 2014)

③ List Price ④ Ex-factory Price with consumption tax

Source: ①,② : Statistics on Pharmaceutical and Medical Device Industry 2012; Ministry of Health, Labour and Welfare (MHLW)

③ : Japan Pharmaceutical Market in 2013; IMS Health

④ : Labour Force Survey 2012; Ministry of Internal Affairs and Communications (MIC)

New Medicines from JAPAN

Number of Global
"Top 100" selling
Medicines (in 2013)

Country	Number of Medicines
USA	53
JAPAN	10
Switzerland	10
Germany	9
UK	6
France	4
Other	2

Innovative New
Medicines from JAPAN

*INN	Developer	Indication
Olmesartan	Daiichi-Sankyo	Hypertension
Candesartan	Takeda	Hypertension
Leuprorelin	Takeda	Prostate Cancer
Tacrolimus	Astellas	Immunosuppression
Solifenacin	Astellas	Overactive Bladder
Rabeprazole	Eisai	Peptic Ulcer

JAPAN's Innovation to Global Health

Global Health Innovative Technology (GHIT) Fund

- Supporting development of vaccines and medicines for infectious diseases in the developing world
- Contributors :
 - Japanese Government (*MHLW and **MOFA)
 - Bill & Melinda Gates Foundation
 - 5 Japanese Pharmaceutical Companies
(Astellas, Daiichi-Sankyo, Eisai, Shionogi, Takeda)

Collaboration between BRAZIL and JAPAN

- Merck, Astellas, Farmanguinhos, and 3 other partners participate in Pediatric Praziquantel Consortium
- Eisai and ***FIOCRUZ are developing a medicine for cerebral malaria

*MHLW: Ministry of Health, Labour and Welfare

**MOFA : Ministry of Foreign Affairs

***FIOCRUZ: Fundação Oswaldo Cruz

JAPAN's Innovative Pipelines



Alogliptin
(Diabetes Mellitus)
Brentuximab Vedotin
(Malignant Lymphoma)
Mifamurtide
(Osteosarcoma)



Daiichi-Sankyo

Combination of
Olmesartan, Amlodipine,
and **Hydrochlorothiazide**
(Hypertension)

Edoxaban
(Anticoagulant)



Enzalutamide
(Prostate Cancer)
Mirabegron
(Overactive Bladder)



Fentanyl
(Cancer Pain *TDDS)
Oxybutynin
(Overactive Bladder *TDDS)



Eribulin
(Breast Cancer)

GHIT Fund

*TDDS : Transdermal Drug Delivery System

(Global Health Innovative Technology Fund)

Further Contribution to BRAZIL

JAPAN's Pharmaceutical Companies' Proposal

Clinical Trial, NDA, GMP

- ① Acceleration of review process for Clinical Trial approval and *NDA
- ② Clarification of the required Clinical Trial for NDA
- ③ Harmonization with **ICH requirements for ***GMP

*NDA: New Drug Application

**ICH: International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use

***GMP: Good Manufacturing Practice

Further Contribution to BRAZIL

JAPAN's Pharmaceutical Companies' Proposal

Compulsory License,
Tariff/Tax, Traceability

- ④ **Not to extend the scope of Compulsory License for medicines**
- ⑤ **Reduction of Tariff rates and improvement of convoluted Tax system for medicines**
- ⑥ **Creation of Traceability environment for medicines**

Further Contribution to BRAZIL

JAPAN's Pharmaceutical Companies' Proposal

Patent, Data, Trade Mark

- ⑦ ANVISA's pre-approval assessment of pharmaceutical Patent to be limited only to the assessment in the light of Public Health
- ⑧ Protection of Patent for second medical use and invention of crystal polymorph
- ⑨ Development of legal systems for Data Protection Period and Patent Term Restoration
- ⑩ Acceleration of examination process for Patent and Trade Mark registration

Muito Obrigado !



**Building a New Partnership
through Pharmaceuticals**



ご清聴いただき、ありがとうございました！